REMARKS/ARGUMENTS

I. Status of the claims

Claims 1, 7, 8, 13, 18, 24, 29, and 31-32 are amended. Claims 2, 4-6, 14-17, 25-28, and 32 are canceled and claims 34-36 are added. Claims 1, 3, 7-13, 18-24, 29-31, and 33-36 are pending with entry of this amendment.

II. Support for the amendments

Support for the amendments can be found in the specification, drawings and original claims. For example, support for "at least 100 contiguous nucleotides" in claims 7, 18 and 29 can be found on page 18, lines 12-17 of the patent application. Support for new claims 34-36 can be found on, e.g., page 20, lines 10-23 of the patent application.

III. Rejection under 35 U.S.C. § 112, second paragraph

Claims 2, 14, 18, 25, and 32 were rejected as allegedly unclear for reciting the phrase "AP1 regulatory element." As amended, the claims do not use the rejected phrase. Accordingly, Applicants respectfully request withdrawal of the rejection.

IV. Written Description Rejection

The Examiner rejected claims 1-3, 7-14, 18-25 and 29-32 as allegedly failing to meet the written description requirement. Specifically, the Examiner argued that the phrase "AP1 regulatory element" encompasses any promoter regulating floral expression and further that the claims encompassed nucleotide deletions, additions and substitutions within the *AP1* promoter. The Examiner argued that the application disclosed an *Arabidopsis* promoter (SEQ ID NO:12), but did not identify "essential regions" of the promoter. Therefore, the Examiner argued that the application did not provide a "representative number of polynucleotide sequences" with *AP1* promoter activity or sufficient "structural features" common to the genus of claimed polynucleotides. Applicants respectfully traverse the rejection.

The independent claims, as amended, relate to embodiments involving a floral regulatory element from an *Arabidopsis AP1* gene. Amended claims 1, 13, 24, 31, and 34 specify that the floral organ selective regulatory element is from an *Arabidopsis AP1* gene. The Examiner has already acknowledged that the present application provides the sequence of one *Arabidopsis AP1* gene promoter. *See, e.g.*, Office Action, top of page 5. While *Arabidopsis* plants have some natural variation in genetic material between ecotypes, Applicants submit that the information provided in the present application, including *AP1* sequences from one ecotype, put those of skill in the art in possession of the sequences recited in the claims. Therefore, those of skill in the art can readily distinguish the claimed invention from other sequences, as required in *University of California v. Eli Lilly and Co.* 119 F.3d 1559 (Fed. Cir 1997).

Further, based on a reading of the present application, those of skill in the art could readily generate fragments of *AP1* genes that direct expression in floral organs. As the Examiner likely understands, while promoters contain a variety of elements controlling expression from the promoter, large parts of the 5' region of genes can generally be deleted without significant effect on promoter function. Indeed, a common tool of promoter analysis is promoter deletion studies, which can be used to delimit the active region of a promoter. *See, e.g.*, page 20, lines 10-23 of the present specification, describing an example of a method for identifying fragments with activity.

This information is particularly relevant for claims directed to fragments comprising at least 100 contiguous nucleotides of SEQ ID NO:12. Such claims clearly meet the written description requirement as the fragments are obtained directly from the sequence provided in the specification. Claims directed to fragments comprising at least 100 contiguous nucleotides of SEQ ID NO:12 include claims 7, 18, 29, and 36.

Moreover, new claims 34-36 are directed to methods of generating floral specific active fragments of AP1 promoters and subsequent expression of cytotoxic gene products using floral-selective promoter fragments. This method involves identifying floral selective regulatory elements within a gene and requires no *a priori* knowledge of gene or promoter sequences aside from what is provided in the patent application. Therefore new claims 34-36 meet the requirements of the written description requirement.

In view of the above discussion, Applicants submit that the subject matter of the claims as amended is described in the application sufficiently to meet the written description requirement. Therefore, the Examiner is respectfully requested to withdraw the rejection.

V. Enablement Rejection

The Examiner rejected claims 1-3, 7-14, 18-25 and 29-33 as allegedly not enabled for the entire scope of the claims. As discussed above with reference to the written description rejection, the Examiner argued that the phrase "AP1 regulatory element" encompasses any promoter regulating floral expression and further that the claims encompass nucleotide deletions, additions and substitutions within the *AP1* promoter. The Examiner argued that the application disclosed an *Arabidopsis* promoter (SEQ ID NO:12), but did not identify "essential regions" of the promoter. Moreover, the Examiner argued that the art teaches that activity of some unrelated promoters can be altered with specific nucleotide changes. *See*, Office Action, page 8. Therefore, the Examiner argued that a large number of inoperable embodiments would have to be analyzed to identify functional floral regulatory elements within the scope of the claims. *See*, page 10 of the Office Action. Applicants respectfully traverse the rejection.

To establish a *prima facie* case of non-enablement, the Examiner must show that undue experimentation would be required to make and use the claimed invention. Even if the practice of the claimed invention requires a considerable amount of experimentation, it is not necessarily "undue" experimentation:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or it the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) (citing *In re Angstadt*, 190 USPQ 214 (CCPA 1976). MPEP § 2164.06.

In the present case, "undue experimentation" is not required to practice the full scope of the invention. As discussed above, an *Arabidopsis AP1* gene sequence was provided in the patent application. While the exact position of floral selective regulatory regions of the promoter are not identified, one of the most routine techniques in molecular biology involves

deletion analysis of promoters. Applicants submit that routine promoter deletion studies do not amount to "undue" experimentation. The application provides a sequence from an *Arabidopsis AP1* gene thereby providing a basis for generating promoter deletions using routine molecular biology methods. Thus, those of skill in the art could have readily used an *AP1* gene described in the specification or otherwise isolated from *Arabidopsis* and constructed a series of deletions and tested each deletion for activity. Thus, at most, routine experimentation would be required to practice the claimed invention.

Finally, as discussed above, new claims 34-36 are directed to methods of generating floral selective fragments of *AP1* genes and subsequent expression of cytotoxic gene products using the identified floral-selective promoter fragments. As this method involves only routine techniques and requires no *a priori* knowledge of gene or promoter sequences aside from what is provided in the patent application, new claims 34-36 are enabled.

In view of the above discussion, Applicants submit that the subject matter of the claims as amended is described in the application to enable those of skill in the art to make and use the claimed invention. Therefore, the Examiner is respectfully requested to withdraw the rejection.

VI. Art Rejections

The Examiner rejected claims 1-3, 7-10, 13-14, 18-21, 24-25 and 20 as allegedly anticipated by Day *et al.* The Examiner argued that an "AP1 regulatory element" encompassed any regulatory element that mediated floral selective gene expression. In view of this interpretation, the Examiner argued that Day *et al.*, which allegedly describes an AP3 genomic clones linked to a nucleic acid encoding diphtheria toxin A, anticipated the claims.

The Examiner also argued that while Day *et al.* did not describe transgenic woody plants or trees or kits, it was allegedly obvious to make such compositions in view of Day *et al.*

Applicants respectfully traverse the prior art rejections. The Examiner's interpretation of the claims makes no sense in that it suggests that an AP3 genomic clone anticipates claims directed to an AP1 regulatory element. Indeed, it is not clear how the Examiner can restrict the claims between different types of regulatory elements (e.g., AP1,

AGL2, AGL4, etc.) in one action and then argue in a second action that the gene designations do not provide any meaning as claim limitations.

Nevertheless, the present claims do not use the term "AP1 regulatory element." As amended, the claims refer at a "floral organ selective regulatory element from an *AP1* gene." Day *et al.* describes an AP3 genomic clone, **not** a sequences from an *AP1* gene. Therefore, Day *et al.* does not teach or suggest the subject matter of the pending claims. Withdrawal of the anticipation and obviousness rejections is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

Matthew E. Hinsch
Reg. No. 47,651

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 415-576-0200
Fax: 415-576-0300
Attachments
MEH:meh
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